UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KIMBERLY GREMO, Plaintiff, v. BAYER CORPORATION; BAYER HEALTHCARE LLC; BAYER HEALTHCARE PHARMACEUTICALS, INC.; GE HEALTHCARE, INC.; GENERAL ELECTRIC COMPANY; MALLINCKRODT, INC.; MALLINCKRODT LLC; GUERBERT LLC; LIEBEL-FLARSHEIM COMPANY LLC; AMERISOURCE BERGEN CORPORATION; AMERISOURCE BERGEN DRUG CORPORATION, Defendants.	Civil Action No. 1:19-cv-13432-NLH-AMD Honorable Noel L. Hillman, U.S.D.J. Honorable Ann Marie Donio, U.S.M.J. **ORAL ARGUMENT REQUESTED**

BRIEF IN SUPPORT OF DEFENDANTS BAYER CORPORATION, BAYER HEALTHCARE LLC AND BAYER HEALTHCARE PHARMACEUTICALS INC.'S MOTION TO DISMISS THE AMENDED COMPLAINT

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Bayer moves to dismiss Plaintiff's Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) because it fails to state a claim upon which relief can be granted.[1] This motion supplants Bayer's earlier motion to dismiss, since Plaintiff has now filed an Amended Complaint abandoning ***six*** causes of action Bayer sought to dismiss in the initial Complaint.[2]

First, Plaintiff's claims, as pled, are preempted. "[T]o state a claim for failure-to-warn that is not preempted by the [Food, Drug, and Cosmetic Act], a plaintiff must plead a labeling deficiency that [Defendants] could have corrected using the ['Changes Being Effected,' or 'CBE'] regulation." *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019) (internal quotation marks omitted). Plaintiff pleads nothing showing Bayer could have used the CBE regulation to change the label of its product Magnevist to include her desired warning: that gadolinium retention causes certain injuries to persons with normal kidney function. In fact, two other federal courts have recently held that "***Plaintiff's failure-to-warn claims [were] preempted***" in a case alleging "injuries sustained as a result of exposure to Magnevist" in a patient with normal kidney function. *McGrath v. Bayer HealthCare Pharm. Inc.*, No. 1:18-cv-02134, --- F. Supp. 3d ---, 2019 WL 2582530, at *1, *5 (E.D.N.Y. June 24, 2019) (emphasis added); *see also Klein v. Bayer HealthCare Pharm. Inc.*, No. 2:18-cv-01424, 2019 WL 3945652, at *5 (D. Nev. Aug. 21, 2019). And Plaintiff's design defect claim is also preempted because Bayer could not have made a unilateral change to Magnevist's design after its approval by the FDA. *See* 21 C.F.R. § 314.70(b)(2)(i).

[1] Defendants Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc. will be referred to collectively as the "Bayer Defendants" or "Bayer." Plaintiff Kimberly Gremo will be referred to as "Plaintiff."

[2] Plaintiff filed the Original Complaint on April 24, 2019, and Bayer later filed its initial Rule 12(b)(6) motion to dismiss on August 12, 2019, Dkt. No. 61.

Second, Plaintiff's claims are barred by New Jersey's statute of limitations. *See* N.J.S.A. § 2A:14-2 (two-year statute of limitations for products liability claims). Judicially noticeable materials show that Plaintiff was aware of her injuries and believed they were related to GBCAs in 2015—or earlier—thus commencing the relevant two-year statute-of-limitations period under New Jersey law. Plaintiff's claims are therefore barred as this action was not filed until April 24, 2019, more than four years later.

Finally, Plaintiff's claims, including her request for punitive damages, are not cognizable under the New Jersey Product Liability Act ("NJPLA") or violate federal pleading rules. Plaintiff's warning-based claims are barred by New Jersey's super-presumption of adequacy for FDA-approved warnings; her breach-of-warranty claim fails because she does not plead any particular warranty; her claims for punitive damages are not permitted by the NJPLA; and she fails to plead an injury that can support her claims under New Jersey law.

Bayer thus asks that the Court dismiss Plaintiff's Amended Complaint with prejudice.

I. BACKGROUND: PLAINTIFF'S UNRECOGNIZED DISEASE AND HER DISMISSAL OF CLAIMS FOLLOWING BAYER'S FIRST MOTION

Magnevist is an FDA-approved gadolinium-based contrast agent ("GBCA") marketed by Bayer and administered intravenously by medical professionals to enhance the quality of magnetic resonance imaging ("MRI") to diagnose serious conditions, such as cancer, strokes, and aneurysms. Plaintiff, a New Jersey resident, filed an Amended Complaint on August 20, 2019 asserting four causes of action related to her alleged exposure to Magnevist and the GBCAs marketed by the other named defendants during 10 MRIs between August 2007 and December 2016. *See* Am. Compl. ¶¶ 4-72, 164. Plaintiff alleges exposure to Bayer's GBCA – Magnevist – on only one occasion on July 15, 2014. *Id*. at ¶ 164.

A. The FDA's Rejection of Plaintiff's Alleged "Gadolinium Deposition Disease" as a Real Disease

Plaintiff alleges that "[a]s a direct and proximate result of [her] exposure to each and all of Defendants' GBCAs, [she] has retained gadolinium," which caused her to develop a condition she calls "gadolinium toxicity, or Gadolinium Deposition Disease (GDD), as characterized by a multitude of symptoms," including the following:

> [S]kin issues including rashes, dermatitis, burning, hyperpigmentation, rough patches, loss of elasticity, peeling and callus like buildup; teeth issues including darkened teeth and spots, cracking, and sensitivity; neurological issues including brain fog and memory loss; pain including hip, back, bone and joint; neuropathy; fatigue; muscle aches and fasciculation; and loss of smell.

Id. at ¶¶ 166-67.

"Gadolinium Deposition Disease" is not a "disease" recognized by the medical community. It is a catch-all term used by plaintiffs' lawyers for a nonspecific collection of symptoms supposedly experienced by some patients who use GBCAs. As a federal court recently concluded in granting defendants' *Daubert* motions to exclude all medical causation testimony about "GDD" and other alleged symptoms proffered by the same counsel representing Plaintiff in this case, an FDA advisory committee rejected the idea that "GDD" is a real disease caused by GBCAs after thorough investigation of exactly this subject in 2017:

> The FDA prepared a lengthy briefing document . . . and [the FDA's Medical Imaging Drugs Advisory Committee ("MIDAC")] then held a conference on September 8, 2017, where it heard presentations from FDA medical officers, invited scholars, industry representatives, and the public. . . After considering all of the evidence and hearing presentations from scholars, experts, and patient advocacy groups, **MIDAC unanimously concluded that the medical and scientific evidence does not establish that GBCAs cause GDD**. This does not appear to have been a difficult decision for the committee members – there was no equivocation in their views.

Davis v. McKesson Corp., No. CV-18-1157, 2019 WL 3532179, at *5 (D. Ariz. Aug. 2, 2019) (emphasis added). Plaintiff's claims that any negative medical consequences result from alleged

trace retention of gadolinium in patients with normal kidney function also contradict numerous public FDA statements, including that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function," which includes Plaintiff.[3] *See* Certification of Wilfred P. Coronato, Esq. ("Coronato Cert."), Ex. A,[4] 12/19/2017 FDA Safety Announcement at 2, https://www.fda.gov/Drugs/DrugSafety/ucm589213.htm; *see also* Am. Compl. ¶¶ 86, 165 (alleging that Plaintiff had normal kidney function before using GBCAs).

B. Plaintiff's Abandonment of Six of Her Ten Claims in the Amended Complaint

Bayer moved to dismiss Plaintiff's initial Complaint in this action. On August 20, 2019, following Bayer's motion, Plaintiff filed an Amended Complaint that abandoned six of the ten causes of action Bayer had asked the Court to dismiss, including her standalone claim for punitive damages. *See generally* Pl.'s initial Complaint (hereinafter "Compl.") ¶¶ 138-156, 163-204. Despite abandoning six claims, her Amended Complaint is even ***longer*** than the initial one, largely because Plaintiff added voluminous scientific allegations—all irrelevant to her claims—in an attempt to avoid a preemption dismissal. *See* Am. Compl. ¶¶ 83-163.

II. PLAINTIFF'S CLAIMS, AS PLED, ARE PREEMPTED

Recently, in two other cases alleging "injuries sustained as a result of exposure to Magnevist," federal judges have held that the "Plaintiff's failure-to-warn claims [were] preempted" at the motion-to-dismiss stage. *McGrath*, 2019 WL 2582530, at *1, *5; *see also*

[3] Bayer asks that the Court take judicial notice of the cited materials on the FDA's website, as other courts in this circuit have done. *See, e.g., In re Egalet Corp. Sec. Litig.*, 340 F. Supp. 3d 479, 496 (E.D. Pa. 2018) (taking judicial notice of "reports published on the FDA website"). Judicial notice of these documents is appropriate under Fed. R. Evid. 201(b) because material on the FDA's website is "capable of immediate and accurate determination by resort to" the FDA itself, a "source[] whose accuracy cannot be reasonably questioned."

[4] The exhibits named herein are exhibits to the Certification of Wilfred P. Coronato, Esq. ("Coronato Cert.").

Klein, 2019 WL 3945652, at *5 (same). Plaintiff's Amended Complaint, which presents scientific allegations that are very similar to those in the dismissed complaints, has the same deficiency: Plaintiff failed to plead facts showing Bayer could have changed Magnevist's label to include her desired warning that gadolinium retention causes the injuries she claims in persons with normal kidney function.

First, as every court of appeals to consider the question has held, "to state a claim for failure-to-warn that is not preempted by the [Food, Drug, and Cosmetic Act], a plaintiff must plead a labeling deficiency that [Defendants] could have corrected using the ['Changes Being Effected,' or 'CBE'] regulation." *Gibbons*, 919 F.3d at 708 (quotation marks omitted); *see also In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015) (same). In both *McGrath* and *Klein*, the courts held that the plaintiff's claims were preempted because "the Complaint fail[ed] to state a plausible claim that Bayer could have unilaterally changed its label under the CBE regulation" to include the plaintiff's desired warning that gadolinium retention from Magnevist causes negative symptoms in patients with normal renal function. *McGrath*, 2019 WL 2582530, at *5; *Klein*, 2019 WL 3945652, at *4 (same). In this case, the Complaint's allegations suffer from the same deficiency. That requires dismissal of Plaintiff's first and third claims alleging inadequate warnings.[5] *See* Am. Compl. ¶¶ 168-182, 206-211.

Second, even where the defendant possesses new information permitting a label change, which is not the case here, a plaintiff's claim is still preempted if there is "clear evidence that the FDA would not have approved a change to the prescription drug's label." *Gibbons*, 919 F.3d at 708 (quotation marks and brackets omitted); *see also Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1675-76 (2019). In this case, after thorough review, the FDA approved a label

[5] To the extent Plaintiff's fourth count attempts to allege a fraud claim (or any other claim), it is also preempted. *See* Am. Compl. ¶¶ 212-24.

in 2018 stating that "clinical consequences of gadolinium retention ***have not been established*** in patients with normal renal function," which is exactly the opposite of Plaintiff's desired warning.[6] Plaintiff's two warning-based claims should thus be dismissed on this alternative ground.

Third, Plaintiff's design defect claim is also preempted. *See* Am. Compl. ¶¶ 183-205. There is no way Bayer could have made changes to Magnevist's formulation given the regulatory bar on altering a drug's design. *See* 21 C.F.R. § 314.70(b)(2)(i); *Mut. Pharm. Co., Inc., v. Bartlett*, 570 U.S. 472, 477 (2013).

Since Plaintiff fails the requirements for avoiding preemption, her claims should be dismissed at the motion-to-dismiss stage—a juncture where courts often dismiss preempted claims. *See, e.g.*, *In re Celexa*, 779 F.3d at 43 (holding pharmaceutical drug claims preempted at motion-to-dismiss stage); *Gibbons*, 919 F.3d at 709 (same); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011) (reversing the Fifth Circuit's holding that state tort claims against generic manufacturers are not preempted—an issue that had been decided by the district court on a motion to dismiss); *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 672–73 (S.D.N.Y. 2017) ("It is well-established that preemption may be analyzed and decided at the motion to dismiss stage.").

A. Plaintiff Fails to Plead "Newly Acquired Information" that Would Have Allowed Bayer to Unilaterally Add Plaintiff's Desired Warning to Magnevist's FDA-Approved October 2013 Label

Plaintiff fails to plead facts showing Bayer could have added Plaintiff's desired warning to Magnevist's label using the "Changes Being Effected," or "CBE," regulation—which means her failure-to-warn claims are preempted. *Gibbons*, 919 F.3d at 707-08. "[W]hen a party cannot

[6] *See* Coronato Cert., Ex. B, 7/25/2018 Revised Magnevist label at 4 (emphasis added), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf.

satisfy its state duties without the [FDA's] special permission and assistance," those state duties "are pre-empted." *Mensing*, 564 U.S. at 623-24.

That means Plaintiff must show that "the defendants could ***unilaterally*** change the label without FDA approval" to escape preemption. *Byrd v. Janssen Pharm., Inc.*, 333 F. Supp. 3d 111, 120 (N.D.N.Y. 2018) (emphasis added) (quotation marks and ellipses omitted). Otherwise, "[g]enerally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application." *Nelson v. Biogen Idec, Inc.*, No. 12-7317, 2018 WL 1960441, at *13 (D.N.J. Apr. 26, 2018) (citing *Wyeth v. Levine*, 555 U.S. 555, 568 (2009)). *See also Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 184-85 (S.D.N.Y. 2016) ("[F]ederal law expressly forbids a manufacturer from changing its label after the label has received FDA approval unless such changes are made pursuant to the CBE regulation."). Thus, as the Second Circuit recently stated,

> ***[T]o state a claim*** for failure-to-warn that is not preempted by the FDCA, a plaintiff ***must plead*** "a labeling deficiency that [Defendants] could have corrected using the CBE regulation."

Gibbons, 919 F.3d at 708 (emphases added) (alteration in original) (quoting *In re Celexa*, 779 F.3d at 41).

1. Plaintiff Fails to Plead Facts Showing Bayer Could Have Changed Magnevist's Label

Plaintiff fails to plead facts satisfying the CBE regulation—to do that, she must show Bayer received "newly acquired information" ***after*** the FDA approved the ***particular product label*** operative when she used Magnevist, and that the new information demonstrated Magnevist caused "a clinically significant" "hazard" or "adverse reaction[]." *See* 21 C.F.R. §§ 201.57(c)(6)(i); 314.3(b); 314.70(c)(6)(iii); *Maze v. Bayer Healthcare Pharm. Inc.*, No. 4:18-CV-21, 2019 WL 1062387, at *2 (E.D. Tenn. Mar. 6, 2019). Since preemption bars state tort law

from second-guessing the FDA's approval of a drug label, states may impose liability only if "new information not considered by the FDA" that satisfies the CBE regulation develops ***after*** the FDA approves a particular product label. *Maze*, 2019 WL 1062387, at *1-*3. And to satisfy the CBE regulation, that "new[] . . . information" must provide "reasonable evidence of a causal association" of "a clinically significant" "adverse reaction[]" linked to a drug. *See* 21 C.F.R. § 201.57(c)(6)(i) (standard for label change under CBE regulation); 314.70(c)(6)(iii) (CBE regulation); *see also McGrath*, 2019 WL 2582530, at *3-*4 (applying same to Magnevist). To be "clinically significant," the adverse reaction must "have significant impact on therapeutic decisionmaking," *see* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3946 (Jan. 24, 2006), such as a risk that is "***potentially fatal***, [or otherwise] serious," 21 C.F.R. § 201.57(c)(6)(i) (emphasis added); *see also McGrath*, 2019 WL 2582530, at *3 (stating same standard).

Here, Plaintiff fails to show Bayer could have satisfied these requirements and added Plaintiff's desired warning – that gadolinium retention causes adverse health effects in patients with normal kidney function – between ***June 10, 2014*** and ***July 15, 2014***, the relevant dates. The FDA gave approval in June 2014 for the label that was operative on July 15, 2014, the one and only occasion on which Plaintiff alleges she was exposed to Magnevist.[7] Am. Compl. ¶ 164. Consequently, Plaintiff must allege ***new*** information that arose ***after June 2014*** that satisfied the CBE regulation and permitted Bayer to add her desired warning to Magnevist's label ***by July 15, 2014***. *See Maze*, 2019 WL 1062387, at *3. Plaintiff does no such thing. She alleges ***no information whatsoever*** occurring between June 10, 2014 and July 15, 2014, much less any

[7] *See* Coronato Cert., Ex. C, 6/2014 Magnevist Letter at 1, 3, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/019596Orig1s057,021037Orig1s030ltr.pdf; Coronato Cert., Ex. D, June 2014 Magnevist Label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/019596s057lbl.pdf.

showing "risks of a different type or greater severity or frequency than previously included in submissions to the FDA." *See Gibbons*, 919 F.3d at 708 (citing 21 C.F.R. § 314.3(b)).

Further, nothing in the Complaint shows Bayer could have used the CBE regulation to add Plaintiff's desired warning at ***any time*** before she used Magnevist in July 2014, which is unsurprising given the FDA's public statements showing that, to this day, "clinical consequences of gadolinium retention have not been established in patients with normal renal function."[8] *See also McGrath*, 2019 WL 2582530, at *4-*5 (finding absence of information satisfying CBE regulation as of ***2015***). The Complaint includes absolutely no "newly acquired information" before July 2014 showing that gadolinium retention from intravenous administration of Magnevist causes any "clinically significant" "adverse reaction[]" for patients with normal kidney function, and particularly not Plaintiff's particular alleged injuries such as "teeth issues," "memory loss," or "loss of smell." *See* Am. Compl. ¶ 167; *In re Celexa*, 779 F.3d at 41-42; 21 C.F.R. § 201.57(c)(6)(i). Plaintiff's list of purported scientific developments, which falls far short of the CBE regulation's standard for adding Plaintiff's desired warning to Magnevist's label, includes the following:

- Developments ***after*** Plaintiff's last claimed Magnevist use on July 14, 2014, which are irrelevant since it was impossible for Bayer to have changed the label before Plaintiff's Magnevist use based on this post-use evidence. *See, e.g.*, Am. Compl. ¶¶ 152-54, 156(p); 156(w); 157-59. These alleged developments are also irrelevant because they fall into one or more categories below.

- Developments relating to mere ***retention*** of trace amounts of gadolinium in patients' bodies after using GBCAs—not to any ***adverse reaction*** caused by retention, much less a "clinically significant" one with "significant impact on therapeutic decisionmaking." *See, e.g.*, Am. Compl. ¶¶ 109, 125-142, 146-150, 152-54. *See McGrath*, 2019 WL 2582530, at *4 ("Because Plaintiff's failure-to-warn claims depend upon Bayer's failure to warn of the *risks* of gadolinium retention, plausible allegations that relate only to the *fact* of

[8] *See* Coronato Cert., Ex. B, 7/25/2018 Revised Magnevist label at 4, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf.

gadolinium retention do not suffice.").

- Numerous allegations regarding the effects of GBCAs in persons with impaired kidney function, which are irrelevant since Plaintiff admits that she had normal kidney function when she used GBCAs. *See, e.g.*, Am. Compl. ¶¶ 86 (alleging that Plaintiff had normal kidney function when she used GBCAs), 156(v) (alleging effects in patient with kidney impairment). In particular, Plaintiff makes voluminous allegations about nephrogenic systemic fibrosis ("NSF"), which are irrelevant since Plaintiff never claims to have developed NSF, and Plaintiff admits that NSF affects only persons who, unlike her, have kidney impairment. *See, e.g.*, Am. Compl. ¶¶ 111-123, 156(l), 158-59.

- Conclusory, speculative allegations about GBCAs that cite no specific scientific evidence, *see, e.g.*, Am. Compl. ¶¶ 156(a)-(j), and allege general characteristics about GBCAs that have nothing to do with any purported clinical effect on humans, *see, e.g.*, Am. Compl. ¶¶ 90-105; 156(m)-(o).

- Allegations about methods of administering GBCAs, such as intrathecal administration (i.e., administration into the spinal canal), which Plaintiff does not allege she underwent, and which are unrelated to the intravenous administration (i.e., administration into the veins) approved for GBCAs. *See* Am. Compl. ¶¶ 156(r)-(s); *see also* Coronato Cert., Ex. B, 7/25/2018 Revised Magnevist label at 1 (stating Magnevist is "for intravenous use"), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf

- References to "adverse event reports," which include self-reported anecdotal occurrences by any member of the public, including plaintiff lawyers, and which numerous courts have dismissed as insufficient to show "newly acquired information" satisfying the CBE regulation. *See* Am. Compl. ¶¶ 143-45; *Gibbons*, 919 F.3d at 707 (concluding allegations of adverse event reports in complaint did not overcome preemption-based dismissal); *Maze*, 2019 WL 1062387, at *3 (same). In particular, Plaintiff highlights adverse event reports "in 139 patients," Am. Compl. ¶¶ 143-44, even though an FDA advisory committee concluded, regarding that same data, that "a causal association between these adverse events and gadolinium retention following GBCAs exposure cannot be established." Ex. E, 9/8/2017 MIDAC Briefing Document at 13, https://www.fda.gov/media/107133/download.

- Allegations that do not purport to allege scientific information. *See, e.g.*, Am. Compl. ¶¶ 168-81 (conclusory allegations with no supporting scientific facts).

In short, no pled facts show that Bayer could have used the CBE regulation to alter Magnevist's labeling, and dismissal is therefore warranted. *See McGrath*, 2019 WL 2582530, at *4 (dismissing amended complaint because "it helps precious little to mount scientific minutiae

on top of technical jargon if that information ultimately does not plead a plausible causal association between Magnevist and adverse effects" Plaintiff actually alleges).

2. Plaintiff Fails to Allege Facts Showing that the FDA Lacked Any Information Pleaded in the Complaint

Plaintiff also fails to plead facts showing that any new information pertinent to her alleged injuries was unknown by the FDA—an independent reason her claims are preempted as pled. Bayer can only change Magnevist's label based on "newly acquired information, as th[at] term is defined in 21 C.F.R. § 314.3(b)." *See Gibbons*, 919 F.3d at 708. And "newly acquired information" must "reveal[] risks of a different type or greater severity or frequency than previously included ***in submissions to the FDA***." *Id.* (emphasis added, quotation marks omitted) (quoting 21 C.F.R. § 314.3(b)); *see also McGrath*, 2019 WL 2582530, at *3 (same). In *Gibbons*, the Second Circuit affirmed the dismissal of the plaintiff's complaint that "provide[d] no basis upon which the court could conclude that" any alleged new information "presented a different type of risk than those the company had discussed with the FDA, or [any risk] more severe or more frequent than . . . [those] the government already knew about." 919 F.3d at 708.

In this case, Plaintiff similarly pleads nothing to show that any "new[] . . . information" alleged in the Complaint was different from what the FDA previously knew or what Bayer had discussed with the agency. Since Plaintiff pleads no facts showing that the FDA lacked any of the purported scientific information referenced in the Complaint, Plaintiff pleads no "newly acquired information" that could have justified Bayer revising the Magnevist label through the CBE regulation, and her claims are preempted for that independent reason.

B. Clear Evidence Shows the FDA Would Have Rejected Plaintiff's Desired Warning Had Bayer Added It Using the CBE Regulation

Even if Plaintiff ***had*** pled that Bayer could have changed Magnevist's label using the CBE regulation, which she does not, she still fails to show that the FDA would have allowed the

labeling change she seeks, so her claims are also preempted on that alternative ground. Though manufacturers can change label text unilaterally with the CBE regulation, "the FDA can [later] reject CBE submissions and require manufacturers to revert to the prior version of the label." *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 812 (7th Cir. 2018), *cert. denied*, 139 S. Ct. 2636 (2019). A tort claim requiring a label change is preempted if there is "'clear evidence' that the FDA would not have approved a change to the drug's label." *Albrecht*, 139 S. Ct. at 1672.

Here, the Complaint and associated labeling materials demonstrate that the FDA would have rejected Plaintiff's desired label change: the FDA considered precisely the risk Plaintiff alleges, and then approved a label explicitly denying that scientific evidence demonstrated that risk. In 2017, the FDA convened its Medical Imaging Drugs Advisory Committee ("MIDAC") to discuss "the potential risk of gadolinium retention in the brain and other body organs in patients receiving gadolinium-based contrast agents." *See* Coronato Cert., Ex. F, 8/18/2017 FDA Public Participation Information, Meeting of the MIDAC at 2, https://www.fda.gov/advisory-committees/advisory-committee-calendar/updated-start-time-and-public-participation-information-september-8-2017-meeting-medical-imaging; *see also* Am. Compl. ¶ 146 (noting September 2017 meeting). MIDAC received briefing on GBCAs, and, at the meeting, heard statements from leading scientists, physicians, regulators, and drug manufacturers, as well as members of the public who wished to comment. *See* Coronato Cert., Ex. G, 9/8/2017 MIDAC Meeting Agenda at 1-3, https://www.fda.gov/media/107630/download.

After hearing all the evidence presented, the FDA approved a revised Magnevist label in July 2018 stating that "clinical consequences of gadolinium retention ***have not been established***

in patients with normal renal function."[9] The FDA's approval of this label—particularly after thorough consideration of the very risk Plaintiff claims should have been included in the Magnevist label—is clear evidence that the FDA would have rejected Plaintiff's proposed warning. *See Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1099, 1101-02 (10th Cir. 2017) (holding that "FDA's rejection of [a] citizen petition" requesting a warning, based on the agency's "evaluat[ion of] the scientific merit" of the request and "survey [of] the literature" relevant to the question, was "clear evidence" that the FDA would not have approved the requested warning); *Risperdal and Invega Product Liability Cases*, No. BC599531, 2017 WL 4100102, at *10 (Cal. Super. Ct. Mar. 16, 2017) ("The denial of the Citizens Petition . . . alone also serves to provide 'clear evidence' that the FDA was satisfied with the current . . . label . . . and would not have adopted Plaintiffs' proposed change."). That is particularly so because the FDA's approval of Magnevist's 2018 label reflected "the agency's formal, authoritative conclusions regarding the conditions under which [Magnevist] can be used safely and effectively," *Utts*, 226 F. Supp. 3d at 184, and required the agency to conclude "'based on a fair evaluation of all material facts,' that [Magnevist's label was] not 'false or misleading in any particular.'" *In re Celexa*, 779 F.3d at 36 (quoting 21 U.S.C. § 355(d)(7) and 21 C.F.R. § 314.125(b)(6)).

None of this is surprising: Plaintiff flatly stated in her initial Complaint that the FDA has never accepted her medical theories or the warnings she believes Bayer should have added to Magnevist's label. Plaintiff alleged that, even in 2018, "***the FDA*** and the GBCA industry . . .

[9] *See* Coronato Cert., Ex. B, 7/25/2018 Revised Magnevist label at 4 (emphasis added), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019596s064s065lbl.pdf; *see also* Coronato Cert., Ex. A, 12/19/17 FDA Safety Announcement at 4, https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-gadolinium-based-contrast-agents-gbcas-are-retained-body ("To date, the only known adverse health effect related to gadolinium retention is a rare condition called nephrogenic systemic fibrosis (NSF) that occurs in a small subgroup of patients with pre-existing kidney failure").

[came] short of acknowledging any untoward health effects from gadolinium retention in non-renal patients" like her. Compl. at ¶ 120 (emphasis added). She further alleged that, "***to date***, ***the FDA*** and the GBCA industry have refused to acknowledge that GBCAs can cause NSF in renal patients but also can cause, in non-renal patients, a variety of NSF-like injuries and symptoms." *Id.* at ¶ 121 (emphasis added.) Accordingly, by her own Complaint, Plaintiff demonstrates that the FDA would have rejected the warnings she believes Bayer should have added.

Moreover, "Congress has imposed on the FDA a duty to initiate a label change if the [agency] becomes aware of new information, including any new safety information[,] that the [agency] determines should be included in the labeling of the drug." *Albrecht*, 139 S. Ct. at 1684 (Alito, J., concurring) (quotation marks and ellipsis omitted) (quoting 21 U.S.C. § 355(o)(4)(A)). Given that the FDA "decline[d] to require [Plaintiff's desired] label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified." *See id.* In light of the FDA's duty to initiate label changes where necessary, and its review of voluminous information and statements on this issue, its decision to approve the current labeling further shows "clear evidence" that Plaintiff's proposed contrary label would have been rejected, which means Plaintiff's claims are preempted.

C. Plaintiff's Design Defect Claims Are Preempted

Plaintiff's design defect claim is also preempted. *See* Am. Compl. ¶¶ 183-205. "Once a drug . . . is approved, the manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." *Bartlett*, 570 U.S. at 477 (citing 21 C.F.R. § 314.70(b)(2)(i)) (quotation marks omitted). Plaintiff makes no argument – and there is none – for how Bayer could have made unilateral changes to Magnevist's formulation given the regulatory bar on altering a drug's design. *See* 21 C.F.R. § 314.70(b)(2)(i). Nor can Plaintiff argue that

Bayer should have stopped selling Magnevist, an FDA-approved drug, because of alleged risks. *See Bartlett*, 570 U.S. at 488 (describing a "stop-selling" requirement as "incompatible with our pre-emption jurisprudence").

III. PLAINTIFF'S CLAIMS ARE BARRED BY THE TWO-YEAR STATUTE OF LIMITATIONS

Plaintiff's claims are also time barred because judicially noticeable materials demonstrate that she was aware of her alleged injuries more than two years before filing suit. Under New Jersey law, a products liability action must be commenced within "two years . . . after the cause of action shall have accrued." *Yarchak v. Trek Bicycle Corp.*, 208 F. Supp. 2d 470, 478-79 (D.N.J. 2002) (quoting N.J.S.A. § 2A:14-2). A claim accrues, and the two-year period begins to run, when the plaintiff "discovers, or by the exercise of reasonable diligence and intelligence ***should have discovered***, that he may have a basis for an actionable claim." *Id.* (emphasis added) (citing *Staub v. Eastman Kodak Co.*, 320 N.J. Super. 34, 42-43 (App. Div. 1999)). To satisfy this standard, a plaintiff must merely be aware of facts which suggest the "***possibility***" that another is at fault:

> "Fault" in the context of the discovery rule is **simply that it is possible** – not provable or even probable – that a third person's conduct that caused the injury was itself unreasonable or lacking in due care. In other words, knowledge of fault does not mean a knowledge of a basis of legal liability or a provable cause of action; knowledge of fault denotes only facts suggesting the **possibility of wrongdoing**.

Savage v. Old Bridge-Sayreville Med. Grp., P.A., 134 N.J. 241, 248 (1993) (emphases added); *see also Burd v. N.J. Tel. Co.*, 76 N.J. 284, 293 (1978) ("[t]he proofs need not evoke a finding that plaintiff knew for a certainty that the factual basis was present. It is enough that plaintiff had or should have discovered that he '***may have***' a basis for a claim" (emphasis added)). "[A] plaintiff need not be informed by an attorney that a viable cause of action exists," *Kendall v. Hoffman-La Roche, Inc.*, 209 N.J. 173, 193 (2012) (citing *Burd*, 76 N.J. at 291), "nor does a

plaintiff need to understand the legal significance of the facts," *id*. Thus, triggering the discovery rule and commencing the two-year statute of limitations is a low bar, and neither "medical confirmation" of a possible causal connection nor an "exact diagnosis of [a plaintiff's] asserted medical condition" is needed before the statute of limitations will begin to run. *Yarchak*, 208 F. Supp. 2d at 487; *Lapka v. Porter Hayden Co.*, 162 N.J. 545, 557 (2000).

Here, judicially noticeable materials show that Plaintiff was aware of her injuries and believed there was a possibility that her injuries were related to GBCAs in 2015 – or earlier – thus commencing the relevant two-year statute-of-limitations period under New Jersey law. *See* N.J.S.A. § 2A:14-2. On January 26, 2015, Plaintiff's husband Larry Gremo, on behalf of his wife, created a "GoFundMe" page, which is a website that provides a platform to individuals, groups, and organizations to raise money on the internet.[10] *See* Coronato Cert., Ex. H, *How GoFundMe Works*, GoFundMe, https://www.gofundme.com/c/how-it-works. On Plaintiff's GoFundMe page, her husband sought to raise funds for chelation therapy – a treatment frequently used by persons claiming that they suffer from "gadolinium toxicity" or "Gadolinium Deposition Disease." *See, e.g.*, Coronato Cert., Ex. I, 9/8/2017 MIDAC Meeting Transcript Excerpts at 293-98, https://www.fda.gov/media/108935/download (stating that patient claimed to have "gadolinium poisoning" and traveled to receive "chelation treatments" and "over 40 IVs of chelation").

Specifically, on Plaintiff's GoFundMe page, her husband posted that:

[10] Defendant respectfully requests that the Court take judicial notice of Plaintiff's GoFundMe page. Courts have not hesitated to take judicial notice of various websites that are instructive or responsive to a key issue in the case. *See, e.g.*, *Walsh v. Zickefoose*, No. 12-3961, 2013 WL 504600, at *6 (D.N.J. Feb. 8, 2013) (taking judicial notice of federal prisoner's projected release date from inmate locator website); *Harris v. Midland Credit Mgmt., Inc.*, No. 15-4453 (SDW)(SCM), 2016 WL 475349, at *2 n.4 (D.N.J. Feb. 8, 2016) (taking judicial notice of the Defendant's website which identified it as an affiliate of Midland Funding); *Sanofi-Aventis U.S., LLC v. Mylan GmbH*, No. 17-9105 (SRC), 2019 WL 2067373, at *11 (D.N.J. May 9, 2019) (taking judicial notice of the website "dictionary.com" and its definition of "clicker").

> [Plaintiff] needs your help! **After visiting doctor after doctor and multiple trips to mayo clinic** she is being **diagnosed with heavy metal poisoning**! As of now there is no cure for this and she will need to go through many different trial stages and possably [sic] **Chelation**! Chelation and certain meds are not covered by her insurance and with her not being able to move half the time she's very strapped financially!

See Coronato Cert., Ex. J, Larry Gremo, *Kim's get well campaign*, GOFUNDME (Jan. 26, 2015), https://www.gofundme.com/kvopu4 (emphases added).

Plaintiff alleges that she was exposed to GBCAs on multiple occasions over many years beginning on August 23, 2007. Am. Compl. ¶ 164. Stemming from those exposures, Plaintiff further claims that she developed gadolinium toxicity – allegedly a type of heavy metal poisoning. *See id.* at ¶¶ 83 (alleging gadolinium is a metal); 166 (alleging Plaintiff "suffers from gadolinium toxicity, or Gadolinium Deposition Disease (GDD)" as result of her purported exposure to "Defendants' GBCAs" and retention of gadolinium)). Then, on January 26, 2015, Plaintiff's husband initiated a fundraiser on her behalf so as to allow Plaintiff to obtain chelation therapy – a treatment commonly used by persons claiming "Gadolinium Deposition Disease" – for her "heavy metal poisoning," thus referring to the same phenomenon claimed in her Complaint.

As evidenced by the GoFundMe page, Plaintiff "discover[ed], or by the exercise of reasonable diligence and intelligence reasonably should have discovered, that [s]he may have a basis for an actionable claim" by January 26, 2015, *Yarchak*, 208 F. Supp. 2d at 479, and the two-year statute of limitations began to run at that time. By no later than that date (and probably much earlier), Plaintiff was aware that she had been exposed to gadolinium through her MRIs, believed it was the cause of her injuries and was seeking donations toward chelation treatment. Plaintiff's claims are therefore barred as her original Complaint was not filed until April 24, 2019, more than four years later.

Moreover, Plaintiff filed her Amended Complaint more than a week after Bayer raised this same statute-of-limitations challenge in its prior motion to dismiss, but she added no facts to avoid a dismissal on timeliness grounds. Instead, Plaintiff merely makes conclusory statements that "the statute of limitations applicable to this action was tolled, and did not begin to run, until at least Summer 2018." Am. Compl. ¶ 216. Plaintiff does not, and cannot, provide additional support for her claim that she discovered a possible connection between her GBCA exposure and her purported injuries only in "Summer 2018." The Amended Complaint and GoFundMe web page patently convey that Plaintiff – at the very least – "reasonably should have discovered, that [s]he may have a basis for an actionable claim" more than two years before she filed her claims, warranting dismissal on statute of limitations grounds. *Yarchak*, 208 F. Supp. 2d at 479.

As the New Jersey Supreme Court has long held, "[w]hen an injured party sleeps on h[er] rights so long as to let the customary period of limitations expire, the pertinent considerations of individual justice as well as the broader considerations of repose coincide to bar h[er] action." *Yarchak*, 208 F. Supp. 2d at 479 (quotation marks omitted) (quoting *Vispiano v. Ashland Chemical Co.*, 107 N.J. 416, 462 (1987)). This Court should dismiss Plaintiff's Complaint with prejudice since she failed to file her Complaint within the time mandated by New Jersey law.

IV. STATE-LAW DOCTRINES AND FEDERAL PLEADING RULES ALSO WARRANT DISMISSAL OF PLAINTIFF'S CLAIMS

Plaintiff's claims are also barred by New Jersey state law. As set forth below, Plaintiff's failure-to-warn claim does not overcome the super-presumption of adequacy for FDA-approved drugs under New Jersey law. Plaintiff has also failed to properly plead her breach of express warranty claim, and any request for punitive damages under the NJPLA is preempted. In addition, none of her remaining claims are cognizable under New Jersey law. Plaintiff's alleged injuries

are insufficient as a matter of law and are not reasonably foreseeable. Finally, Plaintiff fails to comply with federal pleading rules.

A. Plaintiff's Warning-Based Claims Fail for the Additional Reason that She Cannot Overcome the Super-Presumption of Adequacy of Magnevist's FDA-Approved Warnings

Plaintiff fails to plead any reason her two warning-based claims overcome New Jersey's super-presumption of adequacy for FDA-approved warnings, providing an alternative reason that those claims fail. *See* Am. Compl. ¶¶ 168-82 (count 1 for failure to warn); ¶¶ 206-211 (count 3 for breach of warranty).[11] Under the NJPLA, "[i]f the warning or instruction given in connection with a drug . . . has been approved or prescribed by the [FDA] under the [FDCA] . . . a rebuttable presumption shall arise that the warning or instruction is adequate." N.J.S.A. § 2A:58C-4. The New Jersey Supreme Court has long recognized that this presumption "should be virtually dispositive" of failure-to-warn claims. *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 25 (1999) (concluding that "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be ***virtually dispositive"*** of such claims (emphasis added) (quotation marks omitted)); *Rowe v. Hoffman–La Roche, Inc.*, 189 N.J. 615, 626 (2007); *Kendall*, 209 N.J. at 195 (discussing the "super-presumption" of adequacy).

The New Jersey Supreme Court recently confirmed that there are only three ways to rebut the super-presumption of adequacy of FDA-approved or prescribed warnings:

> The ***first*** pathway is if a plaintiff can establish "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." *Perez*, 161 N.J. at 25, 734 A.2d 1245. The ***second*** is if a plaintiff can demonstrate "economically-driven manipulation of the post-market regulatory process." *McDarby*, 401 N.J. Super. at 63, 949 A.2d 223. The ***third*** is if a plaintiff can prove by clear and convincing evidence that a manufacturer knew or should have known in the postmarketing phase that the drug warnings were inadequate based on the label

[11] To the extent Plaintiff's fourth count attempts to state a fraud claim, it also fails for this reason.

> warning updating requirements in 21 C.F.R. § 201.57(c), 21 C.F.R. § 314.70(c), or any other pertinent federal regulation.

In re Accutane Litig., 235 N.J. 229, 277 (2018) (emphases added).

Plaintiff fails to allege facts that would support any of those bases for overcoming the super-presumption of adequacy of Magnevist's label. ***First***, Plaintiff's Complaint is completely devoid of any fact-based allegations that Bayer deliberately concealed or failed to disclose after-acquired knowledge of the purported effects of gadolinium retention. In fact, Plaintiff alleges—with no factual support—widespread awareness of concerns relating to gadolinium retention dating back more than three decades. Specifically, she alleges that "[s]ince as early 1984, medical and scientific literature have reported on the deposition of toxic gadolinium in animal tissue." Am. Compl. ¶ 125. She further notes that "[t]hroughout the 1990s, evidence showing retention of gadolinium in human patients with kidney insufficiency was mounting," that "**[b]y 2004, evidence clearly began to show deposition of gadolinium in human patients *without* compromised renal function**" and "[s]ince then, studies have continued to indicate that gadolinium from GBCAs remains within people's bodies long after their suggested half-lives." Am. Compl. ¶¶ 129-31 (emphasis added).

Second, Plaintiff has not pleaded and cannot plead that Bayer engaged in economically-driven manipulation of the post-market regulatory process. The Amended Complaint contains no allegation that Bayer resisted, avoided, or delayed labeling changes that the FDA believed were needed due to emerging safety concerns. *See, e.g., McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10, 65 (App. Div. 2008). And the initial Complaint alleged that the FDA and the GBCA industry were ***both*** "forced to acknowledge . . . that GBCA exposure results in gadolinium being retained in the bodies . . . of patients who do not suffer from clinically diagnosed renal impairment" and that the FDA and the GBCA industry ***both*** have come "short of acknowledging

any untoward health effects from gadolinium retention in non-renal patients." Compl. ¶¶ 117-121. Plaintiff alleges not that the FDA has been manipulated by Bayer, but that the FDA and the industry have worked in concert. *See, e.g.*, Am. Compl. ¶ 149 (alleging that "the FDA and the GBCA industry" worked in concert to "finalize[] a new class warning").

Third, as explained above in Section II.A, Plaintiff has not alleged and cannot allege – by clear and convincing evidence or by ***any*** standard of proof – that Bayer knew or should have known in the post-marketing phase that Magnevist's warnings were inadequate based on the label warning updating requirements in 21 C.F.R. § 201.57(c), 21 C.F.R. § 314.70(c), or any other pertinent federal regulation.

In sum, Plaintiff cannot overcome New Jersey's super-presumption of adequacy, which means that in addition to being preempted, her warning-based claims fail on this alternative state-law ground.

B. Plaintiff's Express Warranty Claim Fails Because She Does Not Identify Any Particular Warranty Bayer Supposedly Provided

Plaintiff's express warranty claim fails because she does not plead any specific warranty Bayer supposedly provided or explain how any particular warranty was breached. *See* Am. Compl. ¶¶ 206-11 (breach of warranty claim). To state a claim for a breach of express warranty, Plaintiff "must properly allege: (1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description," and Plaintiff must "specifically state what [the defendant] expressly warranted." *Mendez v. Shah*, 28 F. Supp. 3d 282, 294-295 (D.N.J. 2014); *See also Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 706 (D.N.J. 2011) (citing N.J.S.A. § 12A:2-313). In *Shah*, for example, the plaintiff merely claimed that the defendant made an express warranty

through unspecified statements by "sales and marketing personnel in 'literature, on-line and in television or other advertising.'" 28 F. Supp. 3d at 295. Judge Hillman rejected those contentions, concluding that the "[p]laintiff's statements are general averments and do not allege the specific affirmation, promise or guarantee made by [the defendant] regarding the [device at issue]." *Id.* Judge Hillman also found that "[a]lthough plaintiff refers to advertising and marketing of [the defendant's] products off-label, she does not specifically state what [the defendant] expressly warranted." *Id. See also Sich v. Pfizer Pharm.*, No. 1:17-cv-02828, 2017 WL 4407930, at *3 (D.N.J. Oct. 4, 2017) (express warranty allegations insufficient because plaintiff "failed to present an affirmation, promise, or description," "failed to allege how this missing affirmation, promise, or description became a part of the basis of the bargain for the product," and failed to plead "how the product ultimately did not conform to that affirmation, promise, or description").

Likewise, Plaintiff here baldly asserts that Bayer breached some "express warranty" that its product was safe and fit for its intended use, which had been purportedly conveyed "by way of affirmation, promise, and/or description in their product labeling, marketing, advertising, promotion, and educational efforts." Am. Compl. ¶ 209. Plaintiff never outlines any specific promise supposedly conveyed by Bayer, how that promise became "part of the basis of the bargain," nor how Magnevist failed to conform to the purported promise. Plaintiff cannot merely declare, with no factual basis, that Bayer created an express warranty and breached it because the product was not safe. Courts have rejected similar non-specific and unsubstantiated claims. *See, e.g.*, *Shah*, 28 F. Supp. 3d at 294-96; *Sich*, 2017 WL 4407930, at *3; *Walters v. Carson*, No. 11–6545, 2012 WL 6595732, at *3 (D.N.J. Dec. 17, 2012) (dismissing express warranty claim because plaintiff did not state how the claims allegedly made by Tylenol that its product was merchantable, free from defects, and reasonably fit for the foreseeable use and intended purposes

formed any part of the basis of the bargain). Because Plaintiff failed to plead any facts suggesting the existence of an express warranty, that claim should be dismissed.

C. Plaintiff's Claims in Count IV for "Tolling: Fraudulent Concealment, Discovery Rule and Equitable Estoppel" Are Not Cognizable Under New Jersey Law

The NJPLA provides the sole remedy to a plaintiff bringing a product liability action because the Act "creates an exclusive statutory cause of action for claims falling within its purview." *Repola v. Morbark Indus. Inc.*, 934 F.2d 483, 492 (3d Cir. 1991). The statute provides only three categories of product liability claims:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable, or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J.S.A. § 2A:58C-2. The statute broadly subsumes "product liability action[s]" brought under New Jersey law, a category that includes "any claim or action brought by a claimant for harm caused by a product, **irrespective of the theory underlying the claim**, except actions for harm caused by breach of an express warranty." *Repola*, 934 F.2d at 492 (citing N.J.S.A. § 2A:58C-1(b)(3) (emphasis added)).

Count IV of Plaintiff's Amended Complaint, which purports to assert a cause of action entitled "Tolling: Fraudulent Concealment, Discovery Rule and Equitable Estoppel," is not a cognizable claim under the NJPLA. The Court should therefore summarily dismiss this count – a step commonly taken at this procedural juncture. *See, e.g.*, *Rodriguez v. Ethicon, Inc.*, No. 18-16684, 2019 WL 3406808, at *1 (D.N.J. May 28, 2019) (granting the defendant's partial motion to dismiss numerous claims outlined in the complaint as subsumed by the NJPLA).

D. Plaintiff's Requests for Punitive Damages are Barred Under New Jersey Law

Plaintiff's punitive damages requests are barred by New Jersey law since Magnevist is an FDA-approved drug. *See* Am. Compl. ¶ 89, pp. 34, 37, 39, 41 (seeking punitive damages in the "Wherefore" clauses following the numbered paragraphs for Counts I, II and III, and in the "Prayer for Relief" clause). In her initial Complaint, Plaintiff sought punitive damages in a separate, independent count under New Jersey common law, the NJPLA, and the Punitive Damages Act. Compl. ¶¶ 175-79 (Count VI). She has now removed that claim, but her remaining requests for punitive damages are also improper.

Under New Jersey law, punitive damages are not allowed in cases involving FDA-approved drugs such as Magnevist. The NJPLA bars punitive damages awards in cases involving pharmaceuticals and other products regulated by the FDA:

> **Punitive damages shall not be awarded, if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the [FDA]** under the [FDCA] . . . **and was approved or licensed**; . . . [h]owever, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.

N.J.S.A. § 2A:58C-5 (emphasis added). Thus, the NJPLA's text states that punitive damages are available in cases alleging harm from FDA-approved drugs only "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material or relevant to the harm in question." N.J.S.A. § 2A:58C-5. The Appellate Division has concluded, however, that this exception is preempted. *McDarby*, 401 N.J. Super. at 94. In other words, under the NJPLA and ensuing jurisprudence, punitive damages are ***never*** available in cases involving FDA "approved or licensed" drugs or devices. N.J.S.A. § 2A:58C-5. *See also Becker v. Smith & Nephew, Inc.*, No. 15–2538, 2015 WL 4647982, at *5 (D.N.J. Aug. 5, 2015) (dismissing the plaintiffs' claim for

punitive damages because "[t]he New Jersey Products Liability Act prohibits punitive damages when a device complies with FDA regulations"); *Batchelor v. Procter & Gamble Co.*, No. 14–2424, 2014 WL 6065823, at *6 (D.N.J. Nov. 13, 2014) (dismissing the plaintiffs' claim for punitive damages because "[t]he PLA generally prohibits the award of punitive damages").

Here, it is undisputed that Magnevist has been an FDA-approved drug since 1988. *See* Am. Compl. ¶ 126. For that reason alone, claims regarding Magnevist cannot give rise to a punitive damages award under N.J.S.A. § 2A:58C-5. The NJPLA explicitly precludes the imposition of punitive damages in cases involving "approved or licensed" products like Magnevist, and the only exception to this rule is preempted. Plaintiff cannot obtain punitive damages as a matter of law and all Plaintiff's requests for punitive damages should be dismissed.

E. Plaintiff Fails to Plead an Injury Supporting Her Claims

Further, Plaintiff fails to plead an injury that can support her claims, which means all claims must all be dismissed.

1. Gadolinium "Retention," Standing Alone, Is Not a Freestanding Legally Cognizable Injury

Plaintiff's allegation of "retention" of gadolinium – meaning that trace amounts remain in Plaintiff's body for some time without further symptoms – is not a freestanding legally cognizable injury that may serve as a basis of her claims. Longstanding New Jersey law requires a discernible "'personal physical' injury" for a claim under the NJPLA. *See Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 65 (2008). In *Sinclair*, the class of plaintiffs alleged that they were potentially suffering from serious silent or latent injuries and sought medical monitoring relief to be paid for by the defendants. *Id.* at 56. The New Jersey Supreme Court rejected that contention, holding that the plaintiffs' potential latent injuries "cannot satisfy the definition of harm to state a product liability claim under the PLA." *Id.* at 65. Similarly, in *Koronthaly v. L'Oreal USA, Inc.*,

the Third Circuit found that the plaintiff failed to state an injury-in-fact in claiming that lipsticks contained lead, partly because the plaintiff suffered no adverse health effects. 374 F. App'x 257, 259 (3d Cir. 2010). *See also Batchelor*, 2014 WL 3749160, at *3 (concluding that the plaintiff failed to properly plead "harm" as defined by the NJPLA since "[n]one of the[] damages are the result of 'physical damage' done to [the plaintiff]'s property").

Likewise, in this case, Plaintiff's allegation of mere "retention" of gadolinium, standing apart from her other alleged symptoms, is not a legally cognizable injury. Like the non-injurious lipstick in *Koronthaly* and the "silent injuries" in *Sinclair*, Plaintiff's purported retention of gadolinium is insufficient to state a freestanding "injury" recoverable under the NJPLA. Simply put, product retention alone is not a cognizable "personal physical injury" to individuals like Plaintiff. *See Sinclair*, 195 N.J. at 65.

2. Plaintiff Fails to Plead That Any Harm Allegedly *Caused by* Gadolinium Retention Was Reasonably Foreseeable

Plaintiff fails to plead facts showing that any alleged symptoms of gadolinium retention, including "Gadolinium Deposition Disease" or her long list of claimed side effects such as "teeth issues," "loss of smell," or "memory loss," Am. Compl. ¶ 166-67, were reasonably foreseeable, which means all of her claims fail. "In a failure-to warn case . . . '[t]he manufacturer of a product has a duty to warn about any risk relating to the product that ***it knows or ought to know***,'" *Gendelman v. Blumenstein*, No. 12–6976 (JEI), 2015 WL 3489883, at *4 (D.N.J. June 2, 2015) (emphasis added) (quoting *Feldman v. Lederle Labs.*, 97 N.J. 429, 434 (1984)), but a manufacturer retains no duty to warn of unforeseeable dangers. *See also Mohr v. Yamaha Motor Co., Ltd.*, No. A-5194-10T4, 2013 WL 3762719, at *4 (N.J. Super. Ct. App. Div. July 19, 2013), *certif. denied*, 216 N.J. 363 (2013). Similarly, a design defect claim fails "[w]ithout proof of a

reasonably foreseeable risk, so that 'the omission of the alternative design renders the product not reasonably safe.'" *Grzanka v. Pfeifer*, 301 N.J. Super 563, 579 (App. Div. 1997).

Here, for the same reason Plaintiff fails to allege any newly acquired information allowing Bayer to change Magnevist's label, she does not show Bayer had the requisite knowledge that gadolinium retention caused risks to patients with normal kidney function. *See supra* Sec. II.A. (showing lack of pled evidence permitting Bayer to change Magnevist label). In particular, Bayer had no reason to believe Magnevist causes the long list of particular symptoms Plaintiff alleges in persons with normal renal function. *See* Am. Compl. ¶ 167.

F. Plaintiff's Claims Fail to Satisfy Pleading Rules

Plaintiff's claims also violate pleading requirements, which further merits dismissal.

1. Plaintiff's "Fraudulent Concealment" Allegations Violate Rule 9

To the extent Plaintiff's "fraudulent concealment" allegations are an attempt to state a legal claim, they violate the heightened pleading standard in Rule 9(b), which requires a party to "state with particularity the circumstances constituting fraud." *See* Am. Compl. ¶¶ 212-224; Fed. R. Civ. P. 9(b). The Third Circuit has long held that "a plaintiff in federal court, to comply with Rule 9(b), must allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation and must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged." *See, e.g., Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 778 (3d Cir. 2018) (quotation marks omitted). Plaintiff's vague, conclusory allegations violate these rules. Plaintiff simply alleges unspecified "misrepresentations and omissions that concealed from Plaintiff material facts," *see* Am. Compl. ¶ 213, without any facts alleging the who, what, when, and where required by Rule 9(b). Moreover, Plaintiff's allegations against all defendants lack the particularity necessary to put any specific defendant on notice.

2. Plaintiff's Remaining Claims Do Not Satisfy Rule 8

"To survive a motion to dismiss" under Federal Rule of Civil Procedure 8, "a complaint must contain sufficient factual matter . . . to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted). Pleadings may not consist of mere "labels and conclusions" or "naked assertions devoid of further factual enhancement." *Id.* (brackets and quotation marks omitted). Here, Plaintiff's Amended Complaint is replete with conclusory statements lacking factual basis. Plaintiff's scattershot legal claims provide numerous pages of vague legal conclusions without factual support. For example, Plaintiff alleges that Bayer was negligent in the "design," "development," "manufactur[e]," "research," and "distribution" of Magnevist, even though the Complaint contains no details alleging problems with these activities. *See* Am. Compl. ¶ 1.

CONCLUSION

For the foregoing reasons, Bayer respectfully requests that this Court dismiss Plaintiff's Amended Complaint with prejudice.

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Respectfully submitted,

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